

### **REMARKS**

The Examiner has objected to the form of claim 16, originally in the form of a use claim. Claim 16 has accordingly been amended to a method of treatment claim. Claims 1, 2 and 14 have also been amended to correct typographical errors.

#### **I. Restriction Requirement**

Applicants hereby provisionally elect for further prosecution in this application the invention identified in the Office Action at page 2 as Group I: "Claims 1 and 16 in part, 3-13 and 17, drawn to a method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-1R antibody wherein the disorder is multiple myeloma, classified in class 424, subclass 130.1." This election is made with traverse.

Applicants respectfully traverse this restriction requirement as improper because it does not comply with the MPEP.

The criteria for restriction are set forth in section 803 of the MPEP as follows:

There are two criteria for a proper requirement for restriction between patently distinct inventions:

- (A) The inventions must be independent or distinct as claimed;  
and
- (B) There would be a serious burden on the examiner if restriction is not required. (emphasis added; internal citations omitted).

Section 803 goes on to state that "Examiners must provide reasons and/or examples to support conclusions." Section 808.01 further requires that

The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given.

The Examiner has not alleged a "serious burden" in connection with the restriction requirement as required by the second prong of § 803, so for that reason alone the antibody restriction should be withdrawn. Even if a serious burden were alleged, however, the Examiner has not, and cannot, make a *prima facie* showing that such burden exists. Section 803 instructs that a "serious burden" may be *prima facie* shown by demonstrating one of three elements:

- (A) the inventions have a separate classification;
- (B) the inventions have a separate status in the art; or,
- (C) the inventions have a different field of search, as defined in MPEP § 808.02.

Of the nine allegedly different inventions into which the Examiner has divided the pending claims, the Examiner has stated that the claims of Groups I through VIII are all classified in class 424, subclass 130.1. There is no allegation that this classification, or the resulting field of search, would differ depending upon which of the Inventions is elected. Similarly there is no allegation that the methods of Groups I through VIII would have "separate status in the art" from treatment with another of these antibodies. Presumably if methods using different antibodies had "separate status in the art," they would be separately classified. That is clearly not the case here.

Moreover, the Examiner acknowledges that all of these eight groups include claims 1 and 3-17. (Applicants would argue that all groups include claim 2 in part as well, as it does not exclude treatment of multiple myeloma, the subject of Group I.) To require the filing of separate divisional applications directed to Groups I through VIII will result in the very same searches of the very same claims being repeated at a later date. It is submitted that these duplicate searches would be quite inefficient to the operation of the Patent and Trademark Office. This inefficiency is unnecessary given that a single search covering all of the claims in Groups I through VIII can be performed in connection with the present application without any serious burden on the Office.

As clearly stated in § 803, "[i]f the search and examination of all the claims in an application can be made without serious burden, the examiner *must* examine them on the merits" (emphasis added). Accordingly, as to Inventions I through VIII the Restriction Requirement should be withdrawn.

## **II. Species Election Requirements**

Pursuant to the species election requirements for Groups I-VI set forth at pages 9-11 of the Office Action, Applicants provisionally elect the specific methods of treatment resulting from the following elections of species:

- (a) the agent species (iv) "analgesic";
- (b) the vaccine species (xii) "autologous tumor vaccines";
- (c) the anti-proliferative agent species (xviii) "PDGFR inhibitors";
- (d) the antibody species (xx) "2.13.2";
- (e) the VH gene species (xxvii) "VH DP-47"; and
- (f) the VL gene species (xxx) "A30".

Applicants believe that claims 1-3, 5, 6, 8-13, 16, and 17 read upon the selected species. It is understood that upon the allowance of a generic claim, Applicant will be

entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim.

Applicants expressly reserve the right to file at a later date one or more divisional applications directed to the subject matter of the non-elected groups.

This Response is accompanied by a Petition for Revival of Unintentionally Abandoned Application Under 37 CFR § 1.137(b) together with the requisite petition fee under 37 CFR § 1.17(m). Applicants believe that no additional fees are due with respect to the filing of this paper. However, if any additional fees are required in connection with the filing of this paper, the Commissioner is hereby authorized to charge Deposit Account Number 16-1445.

In the event that there are any questions relating to this Response or to the application in general, the Examiner is requested to telephone the undersigned concerning such questions so that the prosecution of this application can be expedited.

Respectfully submitted,

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